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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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23432 7590 12/08/2009 COOPER & DUNHAM, LLP 30 Rockefeller Plaza 20th Floor NEW YORK, NY 10112				
EXAMINER				
CHEN, CATHERYNE				
ART UNIT		PAPER NUMBER		
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MAIL DATE		DELIVERY MODE		
12/08/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,022

Applicant(s)

MOREIN ET AL.

Examiner

CATHERYNE CHEN

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 5 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The Amendments filed on Aug. 24, 2009 has been received and entered.

Currently, Claims 1-2, 5, 10-14 are pending. Claims 1-2, 5, 10-13 are examined on the merits. Claims 3-4, 6-9 are canceled.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant's election with traverse of fraction A and C of Quillaja Saponaria in the reply filed on Nov. 17, 2008 is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5, 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox et al. (WO 96/11711) for the reasons set forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

Cox et al. teaches saponin preparations from the bark of *Quillaja saponaria* Molina (page 1, lines 4-6) comprising 50-90% by weight of Fraction A of Quil A and from 50-10% by weight of Fraction C of Quil A (page 3, lines 23-25), where fractions Quil A human (QH) designated QH-A, QH-C iscoms are purified (page 10, line 19). Preparations of iscom-matrix and protein-iscoms are made with QH703 or proteins, respectively (page 15, lines 5, 7). The amounts of QH 703 and Quil A confer different immunogenicity (page 16, lines 1-3, 11-13). Preparations of Quil A, QH-C and mixtures of QH-A and QH-C were used to make iscom matrices for dosing mice to study the potential immunomodulatory activity of iscoms made from these various components and mixtures (Example 6). Thus, at least two different saponin fractions of *Quillaja saponaria* Molina in separate iscom particles have immunomodulating activity.

Therefore, the reference is deemed to anticipate the instant claims above.

Applicant argues that there is no anticipation.

In response to Applicant's argument, Applicant's claim is drawn toward two different saponin fractions in separate iscom particles. "Quil A" is defined as semi-purified saponin fraction of *Quillaja saponaria* (see Cox, page 4, lines 1-2). Cox teaches preparation from 50%-90% by weight of fraction A of Quil A and from 50%-10% by weight of Fraction C of Quil A (see page 26, Claim 1). The two separate iscom particles have immunoactivity. Even though, Cox et al. teaches a mixture, the reference also teaches the purified iscom as separate particles (see page 8, Table 1). Thus, the separate components are taught together and anticipate Applicant's claims.

Applicant argues there is non-obviousness.

In response to Applicant's argument, Applicant's claim is drawn towards a saponin fraction comprising 50-70% by weight of fraction A of Quillaja Saponaria Molina and 30-50% by weight of fraction C of Quillaja Saponaria Molina. "Quil A" is defined as semi-purified saponin fraction of Quillaja saponaria (see Cox, page 4, lines 1-2). Cox teaches preparation from 50%-90% by weight of fraction A of Quil A and from 50%-10% by weight of Fraction C of Quil A (see page 26, Claim 1). The two separate iscom particles have immunoactivity. The amounts of Quil A fractions A and C are taught by the reference, the claims are rendered obvious. Furthermore, the result in the response shows fatality only with ISCOM-C (Enclosure 2). It does not show surprising result to render the concentration non-obvious.

Applicant argues that there is unexpected result.

In response to Applicant's argument, the result in the Enclosure 2, page 2, shows ISCOM A + ISCOM C at 83:17 ratio, which is not commensurate in scope with the claimed concentration of 50%-90% by weight of fraction A of Quil A and from 50%-10% by weight of Fraction C of Quil A. Thus, the result is not persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERYNE CHEN whose telephone number is (571)272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Catheryne Chen
Examiner Art Unit 1655

/Michael V. Meller/

Primary Examiner, Art Unit 1655